UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,267	04/23/2001	Carol L. Novak	2001P07304 US	3216

7590 04/06/2004

Siemens Corporation
Intellectual Property Department
186 Wood Avenue South
Iselin, NJ 08830

EXAMINER	
MILLER, RYAN J	

ART UNIT	PAPER NUMBER
2621	

DATE MAILED: 04/06/2004

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/840,267	Applicant(s) NOVAK ET AL.	
	Examiner Ryan J. Miller	Art Unit 2621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-13,18-25 and 31-34* is/are rejected.

7)☒ Claim(s) *9, 14-17, and 26-30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 April 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: The examiner requests that the applicant update the status of the applications first listed on page 1, lines 10-22. These applications are referred to throughout the specification.

Appropriate correction is required.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "124" in Fig. 1 has been used to designate both an eye-tracking device and an unlabeled box. The drawings are further objected to as failing to comply with 37 CFR 1.84(p)(4) because a) reference characters "131" in Fig. 4 and "410" in the specification have both been used to designate the fly-around step, b) reference characters "132" in Fig. 4 and "420" in the specification have both been used to designate the flicker step, c) reference characters "133" in Fig. 4 and "430" in the specification have both been used to designate the interaction step, and d) reference characters "134" in Fig. 4 and "440" in the specification have both been used to designate the slice scrolling step. The drawings are also objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: "A" in Figs. 2 and 3. The drawings are further objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: a) "500" in Fig. 5 and b) "600" in Fig. 6. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are

required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

3. The following quotations of 37 CFR § 1.75(a) and (d)(1) are the basis of objection:

> (a) The specification must conclude with a claim particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention or discovery.
>
> (d)(1) The claim or claims must conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description. (See § 1.58(a)).

4. Claims 5 and 34 are objected to under 37 CFR § 1.75(a) as failing to particularly point out and distinctly claim the subject matter which the applicant regards as his invention or discovery.

Regarding claim 5, the claim language, "at least some of" is vague and indefinite. How many items does "some" comprise? Are two items "some"? Are "three" items some? Clarification of this issue is required.

Regarding claim 34, the claim recites the limitation "said determining step" in line 19. There is insufficient antecedent basis for this limitation in the claim. For examination purposes, the examiner has interpreted this limitation to recite, "said generating step".

5. Claims 1-34 are objected to under 37 CFR § 1.75(d)(1) as failing to find clear support or antecedent basis in the description.

Claims 1, 18, and 34 call for the estimating step to be based on "predefined criteria". However, such "predefined criteria" are not clearly described in the applicant's specification. The applicant does describe that "[a]natomical knowledge is used to reason about the likelihood

that the object of interest corresponds to a nodule" (see applicant's specification: page 14, lines 10-12). Does this "anatomical knowledge" correspond to the claimed "predefined criteria"? Clarification of this issue is required.

Claims 2-17 and 9-33 are objected to as depending from objected to claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 2, 4-8, 11-13, 18, 19, 21-25, and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Summers et al. (U.S. Patent No. 6,556,696 B1) and Kallergi et al. (U.S. Patent No. 6,630,937 B2).

As applied to claim 1, Summers et al. disclose a computer-assisted diagnosis method for assisting diagnosis of anatomical structures in a digital volumetric medical image of at least one lung, comprising the steps of: identifying an anatomical structure of interest in the volumetric digital medical image (see Figs. 2 and 6 and column 8, lines 1-6: The reference describes selecting a seed point to initialize the segmentation process. Therefore, this seed point identifies an anatomical structure of interest. The medical image data is also volumetric as can be seen in Fig. 6.); automatically segmenting, in real-time, the anatomical structure of interest in a predefined volume of interest (VOI) (see Fig. 8 and column 20, lines 41-44: The reference describes that in step 810 the process computes an isosurface of the anatomical structure depicted in the voxel data. This is equivalent to segmenting the anatomical structure of interest.);

automatically computing, in real-time, quantitative measurements of the anatomical structure of interest (see column 17, line 44 – column 18, line 10: The reference describes computing the curvature (i.e. quantitative measurements) of the anatomical structure of interest.); displaying, in real-time, a result of said segmenting step (see Fig. 6 and column 7, lines 16-17: The reference describes that the 3D surface rendered model of the segmented anatomical region of interest is displayed as can be seen in Fig. 6.); estimating, in real-time, a likelihood that the anatomical structure of interest corresponds to a disease or an area warranting further investigation, based on predefined criteria and the quantitative measurements (see column 18, lines 11-40: The reference describes that lesions (i.e. a likelihood that the anatomical structure of interest corresponds to a disease or an area warranting further investigation) are determined based on the mean curvature (i.e. quantitative measurements) and size (i.e. predefined criteria).); and generating, in real-time, a warning, when the likelihood is above a predefined threshold (see column 21, lines 3-11: The reference describes that based on the curvature characteristics, which were previously compared with a threshold value, a lesion on the surface of the anatomical structure of interest is colorized (i.e. generating a warning).).

As applied to claim 4, Summers et al. disclose that the displaying step comprises the step of rendering a colored, three-dimensional representation of the anatomical structure of interest, with background structures, if any, rendered in contrasting colors with respect to the anatomical structure of interest (see column 21, lines 52-55: The reference describes a 3D modeling of the anatomical structure of interest where lesions are painted red and the background is colored a fleshy tone.).

As applied to claim 5, Summers et al. disclose that the quantitative measurements comprise a circularity of the anatomical structure of interest (see column 17, lines 44-49: The reference describes computing the curvature (i.e. circularity) of the anatomical structure of interest.).

As applied to claim 7, Summers et al. disclose that the identifying step is performed automatically (see column 8, lines 4-6: The reference describes that the process selects the seed points without any user intervention (i.e. automatically).).

As applied to claim 8, Summers et al. disclose that there is more than one anatomical structure of interest, and said method further comprises the step of repeating said segmenting, displaying, estimating, and generating steps, to examine each of the more than one anatomical structure of interest one of sequentially and randomly (see column 22, lines 10-15: The reference describes that the software cycles through and displays each lesion in a sequential order for the physicians examination.).

As applied to claim 11, Summers et al. disclose that segmenting and computing steps are performed substantially instantaneously (see Fig. 8: As can be seen in the figure, immediately after the structure is segmented 810, the curvature characteristics are calculated. Therefore, these steps are performed substantially instantaneously.).

As applied to claim 34, Summers et al. disclose a computer-assisted diagnosis method for assisting diagnosis of anatomical structures in a digital volumetric medical image of at least one lung, comprising the steps of: receiving, in real-time, indicia indicating a position of interest within a volume of interest (VOI) of the digital volumetric medical image (see column 8, lines 1-6: The reference describes selecting a seed point to initialize the segmentation process. This seed

point is equivalent to an indicia indicating a position of interest.); automatically segmenting, in real-time, an anatomical structure of interest in the VOI corresponding to the position (see the rejection of claim 1 above); automatically computing, in real-time, quantitative measurements of the anatomical structure of interest (see the rejection of claim 1 above); displaying, in real-time, a result of said segmenting step (see the rejection of claim 1 above); generating, in real-time, a warning, when the anatomical structure of interest is determined to be potentially adverse based on predefined criteria and the quantitative measurements (see the rejection of claim 1 above); and generating, in real-time, a warning, based on an adverse result of said determining step (see the rejection of claim 1 above).

Claims 1 and 34 further call for the step of displaying a result of the computing step. While Summers et al. disclose displaying the anatomical region of interest and making measurements on that anatomical region of interest, the reference does not disclose displaying these quantitative measurements. However, Kallergi et al., in the same field of endeavor of medical image processing, and the same problem solving area of abnormality detection, disclose displaying a result of a computing step (see Fig. 8: As can be seen in the figure, a measurement of the diameter is displayed next to the anatomical area of interest (i.e. 1.44 cm).).

As applied to claim 2, Kallergi et al. disclose that the generating step comprises the step of rendering a visual confidence bar (see column 6, lines 38-41: The reference describes displaying in a separate window the probability that an area of interest is malignant (i.e. a visual confidence bar).).

As applied to claim 6, Kallergi et al. discloses that the identifying step is performed manually by a user (see column 6, lines 34-36: The reference describes that the user selects a region of interest (i.e. identifying step) by clicking with a mouse at the center of the region.).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify Summers et al. by displaying the results of the quantitative measurements and displaying a visual confidence bar as taught in Kallergi et al. because displaying such information would allow the system to be "as natural and intuitive to use by radiologists as possible" (see Kallergi et al.: column 2, lines 7-8). This information would allow radiologists to make a much more accurate diagnosis due to the extra information provided by the system.

Therefore, it would have been obvious to combine Summers et al. with Kallergi et al. to obtain the invention as specified in claims 1 and 2.

Claims 12 and 13 call for a graphical user interface having a main window for displaying an axial view of the at least one lung. While Summers et al. discloses displaying the structure of interest, the reference does not expressly disclose a graphical user interface having a main window for displaying an axial view of the anatomical structure of interest. However, Kallergi et al., in the same field of endeavor of medical image processing, and the same problem solving area of abnormality detection, disclose such a graphical user interface (see Fig. 6).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify Summers et al. by adding a graphical user interface as taught in Kallergi et al. because the addition of such a graphical user interface would "provide software

that is as natural and intuitive to use by radiologists as possible" (see Kallergi et al.: column 2, lines 7-8).

Therefore, it would have been obvious to combine Summers et al. with Kallergi et al. to obtain the invention as specified in claims 12 and 13.

As applied to claims 18, 19, 21-25 and 31-33, which merely call for a system for performing the method claims, the combination of Summers et al. and Kallergi et al. discloses such a system as can be seen in Fig. 9 of Summers et al.

8. Claims 3 and 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Summers et al. (U.S. Patent No. 6,556,696 B1) and Kallergi et al. (U.S. Patent No. 6,630,937 B2), as applied to claim 1 in the rejection above, and further in combination with Spigelman et al. (U.S. Patent No. 6,119,033 A).

Claim 3 calls for the generating step to comprise the step of creating an audible signal. The combination of Summers et al. and Kallergi et al. only disclose generating visual signals during the generating step and do not expressly disclose generating an audible signal. However, Spigelman et al., in the same field of endeavor of medical imaging and the same problem solving area of abnormality detection, disclose producing an audible alarm when an object of interest is detected (see column 25, lines 58-65: The reference describes that an audible signal is provided when an object is detected in the image.).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the combination of Summers et al. and Kallergi et al. by adding the use of an audible alarm as taught in Spigelman et al. because if the signal is audible "the surgeon becomes aware ... even when the surgeon is not looking at the screen" (see Spigelman

et al.: column 25, lines 63-65). This allows the doctor to more accurately determine whether a region is diseased or healthy.

Therefore, it would have been obvious to combine Summers et al., Kallergi et al., and Spigelman et al. to obtain the invention as specified in claim 3.

As applied to claims 20, which merely call for a system for performing the method of claim 3, the combination of Summers et al., Kallergi et al., and Spigelman et al. disclose such a system as can be seen in Fig. 9 of Summers et al.

9. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Summers et al. (U.S. Patent No. 6,556,696 B1) and Kallergi et al. (U.S. Patent No. 6,630,937 B2), as applied to claim 1 in the rejection above, and further in combination with Armato et al. (U.S. Patent Application Publication No. US 2002/0006216 A1).

Claim 10 calls for the computing step to comprise the step of executing a segmentation method that adaptively adjusts segmentation thresholds based on local histogram analysis to determine an extent of the structural object of interest. The combination of Summers et al. and Kallergi et al. fails to disclose such a segmentation method. However, Armato et al., in the same field of endeavor of medical image processing and the same problem solving area of image segmentation, discloses a segmentation method that uses adaptive thresholds based on local histograms (see paragraph [0056]: The reference describes the use of a multiple gray-level thresholding technique applied a gray-level histogram of the area.).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the combination of Summers et al. and Kallergi et al. by adding the segmentation technique taught in Armato et al. because the use of such a segmentation

technique is "a valuable aid to radiologists, thereby facilitating earlier diagnosis of lung cancer" (see Armato et al.: paragraph [0031]).

Therefore, it would have been obvious to combine Summers et al., Kallergi et al., and Armato et al. to obtain the invention as specified in claim 10.

Allowable Subject Matter

10. Claims 9, 14-17, and 26-30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Shapiro et al. (U.S. Patent No. 6,246,782 B1) is pertinent in that the reference describes a system for detecting masses in mammograms that displays a report based on the detection results.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan J. Miller whose telephone number is (703) 306-4142. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo H. Boudreau can be reached on (703) 305-4706. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ryan J. Miller
Examiner
Art Unit 2621

Ryan J. Miller

LEO BOUDREAU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2600